



April 22, 2021

VIA FOIAONLINE.REGULATIONS.GOV

U.S. Environmental Protection Agency

Re: Freedom of Information Act Request: EPA Response to Pesticide Ecological Risk Petition

Dear FOIA Officer:

This is a request under the Freedom of Information Act, 5 U.S.C. § 552, *as amended* (“FOIA”), from the Center for Biological Diversity (“Center”), a non-profit organization that works to secure a future for all species hovering on the brink of extinction through science, law, and creative media, and to fulfill the continuing educational goals of its membership and the general public in the process.

REQUESTED RECORDS

The Center is requesting the records outlined below from the U.S. Environmental Protection Agency (“EPA”):

From November 19, 2020 to the date EPA conducts this search, the records generated in connection to, or mentioning and/or including the Center’s November 19, 2020 Petition to EPA to withdraw the *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency—Endangered and Threatened Species Effects Determinations* (hereinafter “2004 Overview Guidance”). See Attachment A (The Center’s November 19, 2020 Petition to Withdraw 2004 Overview Guidance).

For this request, the term “records” refers to documents, correspondence (including inter and/or intra-agency correspondence as well as correspondence with entities or individuals outside the federal government), emails including attachments, letters, notes, recordings, telephone records, telephone notes, telephone logs, text messages, chat messages, minutes, memoranda, comments, files, presentations, consultations, biological opinions, assessments, evaluations, schedules, papers published and/or unpublished, reports, studies, photographs and other images, data (including raw data, GPS or GIS data, UTM, LiDAR, etc.), maps, and/or all other responsive records, in draft or final form.

This request is not meant to exclude any other records that, although not specially requested, are reasonably related to the subject matter of this request. If you or your office have destroyed or determine to withhold any records that could be reasonably construed to be responsive to this request, I ask that you indicate this fact and the reasons therefore in your response.

Under the FOIA Improvement Act of 2016, agencies are prohibited from denying requests for information under FOIA unless the agency reasonably believes release of the information will harm an interest that is protected by the exemption. FOIA Improvement Act of 2016 (Public Law No. 114-185), codified at 5 U.S.C. § 552(a)(8)(A).

Should you decide to invoke a FOIA exemption, please include sufficient information for us to assess the basis for the exemption, including any interest(s) that would be harmed by release. Please include a detailed ledger which includes:

1. Basic factual material about each withheld record, including the originator, date, length, general subject matter, and location of each item; and
2. Complete explanations and justifications for the withholding, including the specific exemption(s) under which the record (or portion thereof) was withheld and a full explanation of how each exemption applies to the withheld material. Such statements will be helpful in deciding whether to appeal an adverse determination. Your written justification may help to avoid litigation.

If you determine that portions of the records requested are exempt from disclosure, we request that you segregate the exempt portions and mail the non-exempt portions of such records to my attention at the address below within the statutory time limit. 5 U.S.C. § 552(b).

The Center is willing to receive records on a rolling basis.

FOIA's "frequently requested record" provision was enacted as part of the 1996 Electronic Freedom of Information Act Amendments, and requires all federal agencies to give "reading room" treatment to any FOIA-processed records that, "because of the nature of their subject matter, the agency determines have become the subject of subsequent requests for substantially the same records." *Id.* § 552(a)(2)(D)(ii)(I). Also, enacted as part of the 2016 FOIA Improvement Act, FOIA's Rule of 3 requires all federal agencies to proactively "make available for public inspection in an electronic format" "copies of records, regardless of form or format ... that have been released to any person ... and ... that have been requested 3 or more times." *Id.* § 552(a)(2)(D)(ii)(II). Therefore, we respectfully request that you make available online any records that the agency determines will become the subject of subsequent requests for substantially the same records, and records that have been requested three or more times.

Finally, agencies must preserve all the records requested herein while this FOIA is pending or under appeal. The agency shall not destroy any records while they are the subject of a pending request, appeal, or lawsuit under the FOIA. 40 C.F.R. § 2.106; *see Chambers v. U.S. Dept. of Interior*, 568 F.3d 998, 1004 (D.C. Cir. 2009) ("[A]n agency is not shielded from liability if it intentionally transfers or destroys a document after it has been requested under FOIA or the Privacy Act"). If any of the requested records are destroyed, the agency and responsible officials are subject to attorney fee awards and sanctions, including fines and disciplinary action. A court held an agency in contempt for "contumacious conduct" and ordered the agency to pay plaintiff's costs and fees for destroying "potentially responsive material contained on hard drives and email backup tapes." *Landmark Legal Found. v. EPA*, 272 F. Supp.2d 59, 62 (D.D.C. 2003); *see also*

Judicial Watch, Inc. v. Dept. of Commerce, 384 F. Supp. 2d 163, 169 (D.D.C. 2005) (awarding attorneys' fees and costs because, among other factors, agency's "initial search was unlawful and egregiously mishandled and ...likely responsive documents were destroyed and removed"), *aff'd in relevant part*, 470 F.3d 363, 375 (D.C. Cir. 2006) (remanding in part to recalculate attorney fees assessed). In another case, in addition to imposing a \$10,000 fine and awarding attorneys' fees and costs, the court found that an Assistant United States Attorney prematurely "destroyed records responsive to [the] FOIA request while [the FOIA] litigation was pending" and referred him to the Department of Justice's Office of Professional Responsibility. *Jefferson v. Reno*, 123 F. Supp. 2d 1, 6 (D.D.C. 2000).

FORMAT OF REQUESTED RECORDS

Under FOIA, you are obligated to provide records in a readily accessible electronic format and in the format requested. 5 U.S.C. § 552(a)(3)(B) ("In making any record available to a person under this paragraph, an agency shall provide the record in any form or format requested by the person if the record is readily reproducible by the agency in that form or format."). "Readily accessible" means text-searchable and OCR-formatted. *See id.* Pursuant to this requirement, we hereby request that you produce all records in an electronic format and in their native file formats. Additionally, please provide the records in a load-ready format with a CSV file index or Excel spreadsheet. If you produce files in .PDF format, then please omit any "portfolios" or "embedded files." Portfolios and embedded files within files are not readily accessible. Please do not provide the records in a single, or "batched," .PDF file. We appreciate the inclusion of an index.

If you should seek to withhold or redact any responsive records, we request that you: (1) identify each such record with specificity (including date, author, recipient, and parties copied); (2) explain in full the basis for withholding responsive material; and (3) provide all segregable portions of the records for which you claim a specific exemption. *Id.* § 552(b). Please correlate any redactions with specific exemptions under FOIA.

RECORD DELIVERY

We appreciate your help in expeditiously obtaining a determination on the requested records. As mandated in FOIA, we anticipate a reply within 20 working days. *Id.* § 552(a)(6)(A)(i). Failure to comply within the statutory timeframe may result in the Center taking additional steps to ensure timely receipt of the requested materials. Please provide a complete reply as expeditiously as possible. We prefer email, but you may mail copies of records to:

Ann K. Brown
Center for Biological Diversity
P.O. Box 11374
Portland, OR 97211
foia@biologicaldiversity.org

If you find that this request is unclear, or if the responsive records are voluminous, please email me to discuss the scope of this request.

REQUEST FOR FEE WAIVER

FOIA was designed to provide citizens a broad right to access government records. FOIA's basic purpose is to "open agency action to the light of public scrutiny," with a focus on the public's "right to be informed about what their government is up to." *NARA v. Favish*, 541 U.S. 157, 171 (2004) quoting *U.S. Dep't of Justice v. Reporters Comm. for Freedom of Press*, 489 U.S. 749, 773-74 (1989) (internal quotation and citations omitted). In order to provide public access to this information, FOIA's fee waiver provision requires that "[d]ocuments shall be furnished without any charge or at a [reduced] charge," if the request satisfies the standard. 5 U.S.C. § 552(a)(4)(A)(iii). FOIA's fee waiver requirement is "liberally construed." *Judicial Watch, Inc. v. Rossotti*, 326 F.3d 1309, 1310 (D.C. Cir. 2003); *Forest Guardians v. U.S. Dept. of Interior*, 416 F.3d 1173, 1178 (10th Cir. 2005).

The 1986 fee waiver amendments were designed specifically to provide non-profit organizations such as the Center access to government records without the payment of fees. Indeed, FOIA's fee waiver provision was intended "to prevent government agencies from using high fees to discourage certain types of requesters and requests," which are "consistently associated with requests from journalists, scholars, and *non-profit public interest groups*." *Ettlinger v. FBI*, 596 F. Supp. 867, 872 (D. Mass. 1984) (emphasis added). As one Senator stated, "[a]gencies should not be allowed to use fees as an offensive weapon against requesters seeking access to Government information" 132 Cong. Rec. S. 14298 (statement of Senator Leahy).

I. The Center Qualifies for a Fee Waiver.

Under FOIA, a party is entitled to a fee waiver when "disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the [Federal] government and is not primarily in the commercial interest of the requester." 5 U.S.C. § 552(a)(4)(A)(iii). EPA's regulations at 40 C.F.R. § 2.107(l)(1)-(3) establish the same standard.

Thus, EPA must consider six factors to determine whether a request is in the public interest: (1) whether the subject of the requested records concerns "the operations or activities of the Federal government," (2) whether the disclosure is "likely to contribute" to an understanding of government operations or activities, (3) whether the disclosure "will contribute to public understanding" of a reasonably broad audience of persons interested in the subject, (4) whether the disclosure is likely to contribute "significantly" to public understanding of government operations or activities. *Id.* § 2.107(l)(2), (5) whether a commercial interest exists and its magnitude, and (6) the primary interest in disclosure. As shown below, the Center meets each of these factors.

A. The Subject of This Request Concerns "The Operations and Activities of the Government."

The subject matter of this request concerns the operations and activities of the EPA. This request asks for from November 19, 2020 to the date EPA conducts this search, the records generated in connection, or mentioning and/or including the Center's November 19, 2020 Petition to withdraw the 2004 Overview Guidance. See Attachment A.

This FOIA will provide the Center and the public with crucial insight into how EPA's 2004 Overview Guidance regulations work in practice, and specifically the agency's response to the Center's 2020 petition to withdraw the guidance. It is clear that a federal agency's application of its regulations is a specific and identifiable activity of the government, and in this case it is the executive branch agency of EPA. *Judicial Watch*, 326 F.3d at 1313 (“[R]easonable specificity is all that FOIA requires with regard to this factor”) (internal quotations omitted). Thus, the Center meets this factor.

B. Disclosure is “Likely to Contribute” to an Understanding of Government Operations or Activities.

The requested records are meaningfully informative about government operations or activities and will contribute to an increased understanding of those operations and activities by the public.

Disclosure of the requested records will allow the Center to convey to the public information about EPA's implementation of its 2004 Overview Guidance. Furthermore, responsive records will include EPA's response to the Center's petition to withdraw said guidance. Once the information is made available, the Center will analyze it and present it to its over 1.7 million members and online activists and the general public in a manner that will meaningfully enhance the public's understanding of this topic.

Thus, the requested records are likely to contribute to an understanding of EPA's operations and activities.

C. Disclosure of the Requested Records Will Contribute to a Reasonably Broad Audience of Interested Persons' Understanding of EPA's 2004 Overview Guidance.

The requested records will contribute to public understanding of whether EPA's guidance and implementation is consistent with its mission “to protect human health and the environment.”¹ As explained above, the records will contribute to public understanding of this topic.

Activities of EPA generally, and specifically its problematic guidance that adversely affects ecological risk assessment, are areas of interest to a reasonably broad segment of the public. The Center will use the information it obtains from the disclosed records to educate the public at large about this topic. *See W. Watersheds Proj. v. Brown*, 318 F. Supp.2d 1036, 1040 (D. Idaho 2004) (finding that “WWP adequately specified the public interest to be served, that is, educating the public about the ecological conditions of the land managed by the BLM and also how ... management strategies employed by the BLM may adversely affect the environment”).

Through the Center's synthesis and dissemination (by means discussed in Section II, below), disclosure of information contained in and gleaned from the requested records will contribute to a broad audience of persons who are interested in the subject matter. *Ettlinger v. FBI*, 596 F. Supp. at 876 (benefit to a population group of some size distinct from the requester alone is sufficient); *Carney v. Dept. of Justice*, 19 F.3d 807, 815 (2d Cir. 1994), *cert. denied*, 513 U.S.

¹ EPA, *Our Mission and What We Do*, <https://www.epa.gov/aboutepa/our-mission-and-what-we-do> (last visited Apr. 22, 2021).

823 (1994) (applying “public” to require a sufficient “breadth of benefit” beyond the requester’s own interests); *Cnty. Legal Servs. v. Dep’t of Hous. & Urban Dev.*, 405 F. Supp.2d 553, 557 (E.D. Pa. 2005) (in granting fee waiver to community legal group, court noted that while the requester’s “work by its nature is unlikely to reach a very general audience,” “there is a segment of the public that is interested in its work”).

Indeed, the public does not currently have an ability to easily evaluate the requested records, which are not currently in the public domain. *See Cnty. Legal Servs.*, 405 F. Supp.2d at 560 (because requested records “clarify important facts” about agency policy, “the CLS request would likely shed light on information that is new to the interested public.”). As the Ninth Circuit observed in *McClellan Ecological Seepage Situation v. Carlucci*, 835 F.2d 1282, 1286 (9th Cir. 1987), “[FOIA] legislative history suggests that information [has more potential to contribute to public understanding] to the degree that the information is new and supports public oversight of agency operations... .”²[1]

Disclosure of these records is not only “likely to contribute,” but is certain to contribute, to public understanding of how EPA’s guidance has impacted the environment and human health. The public is always well served when it knows how the government conducts its activities, particularly matters touching on legal questions. Hence, there can be no dispute that disclosure of the requested records to the public will educate the public about this topic.

II. Disclosure is Likely to Contribute Significantly to Public Understanding of Government Operations or Activities.

The Center is not requesting these records merely for their intrinsic informational value. Disclosure of the requested records will significantly enhance the public’s understanding of how EPA’s implementation of 2004 Overview Guidance threatens our environment, as compared to the level of public understanding that exists prior to the disclosure. Indeed, public understanding will be *significantly* increased as a result of disclosure because the requested records will help reveal more about this subject matter.

The records are also certain to shed light on EPA’s compliance with its own mission and purpose. Such public oversight of agency action is vital to our democratic system and clearly envisioned by the drafters of the FOIA. Thus, the Center meets this factor as well.

III. Obtaining the Requested Records is of No Commercial Interest to the Center.

Access to government records, disclosure forms, and similar materials through FOIA requests is essential to the Center’s role of educating the general public. Founded in 1994, the Center is a 501(c)(3) nonprofit conservation organization (EIN: 27-3943866) with more than over 1.7 million members and online activists dedicated to the protection of endangered and threatened species and wild places. The Center has no commercial interest and will realize no commercial benefit from the release of the requested records.

² In this connection, it is immaterial whether any portion of the Center’s request may currently be in the public domain because the Center requests considerably more than any piece of information that may currently be available to other individuals. *See Judicial Watch*, 326 F.3d at 1315.

IV. The Center's Primary Interest in Disclosure is the Public Interest.

As stated above, the Center has no commercial interest that would be furthered by disclosure. Although even if it did have an interest, the public interest would far outweigh any pecuniary interest.

The Center is a non-profit organization that informs, educates, and counsels the public regarding environmental issues, policies, and laws relating to environmental issues. The Center has been substantially involved in the activities of numerous government agencies for over 30 years, and has consistently displayed its ability to disseminate information granted to it through FOIA.

In consistently granting the Center's fee waivers, agencies have recognized: (1) that the information requested by the Center contributes significantly to the public's understanding of the government's operations or activities; (2) that the information enhances the public's understanding to a greater degree than currently exists; (3) that the Center possesses the expertise to explain the requested information to the public; (4) that the Center possesses the ability to disseminate the requested information to the general public; (5) and that the news media recognizes the Center as an established expert in the field of imperiled species, biodiversity, and impacts on protected species. The Center's track record of active participation in oversight of governmental activities and decision making, and its consistent contribution to the public's understanding of those activities as compared to the level of public understanding prior to disclosure are well established.

The Center's work appears in over 5,000 news stories online and in print, radio, and TV per month, including regular reporting in such important outlets as *The New York Times*, *Washington Post*, *The Guardian*, and *Los Angeles Times*. Many media outlets have reported on the plight of endangered and threatened species utilizing information obtained by the Center from federal agencies, including EPA. In 2020, almost three million people visited the Center's extensive website, viewing pages more than 5.3 million times. The Center sends out more than 500 action alerts per year to more than 1.7 million members and supporters. Three times a year, the Center sends printed newsletters to more than 84,300 members. More than 579,000 people follow the Center on Facebook, and there are regular postings regarding environmental protection. The Center also regularly tweets to more than 98,900 followers on Twitter. The Center intends to use any or all of these far-reaching media outlets to share with the public information obtained as a result of this request.

Public oversight and enhanced understanding of the EPA's duties is absolutely necessary. In determining whether disclosure of requested information will contribute significantly to public understanding, a guiding test is whether the requester will disseminate the information to a reasonably broad audience of persons interested in the subject. *Carney*, 19 F.3d 807. The Center need not show how it intends to distribute the information, because "[n]othing in FOIA, the [agency] regulation, or our case law require[s] such pointless specificity." *Judicial Watch*, 326 F.3d at 1314. It is sufficient for the Center to show how it distributes information to the public generally. *Id.*

V. Conclusion

For all of the foregoing reasons, the Center qualifies for a full fee waiver. We hope that EPA will immediately grant this fee waiver request and begin to search and disclose the requested records without any unnecessary delays.

If you have any questions, please contact me at foia@biologicaldiversity.org. All records and any related correspondence should be sent to my attention at the address below.

Sincerely,

A handwritten signature in black ink, appearing to read "Ann K. Brown", with a stylized, flowing script.

Ann K. Brown
Open Government Coordinator
CENTER FOR BIOLOGICAL DIVERSITY
P.O. Box 11374
Portland, OR 97211-0374
foia@biologicaldiversity.org

Attachment

Attachment A (The Center's November 19, 2020 Petition to Withdraw 2004 Overview Guidance)

Attachment A



Petition to Withdraw a Guidance Document

November 19, 2020

Via U.S. Mail

To:

Andrew Wheeler
Administrator
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Alexandra Dunn
Assistant Administrator OCSPP
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

I. Petitioner Information

Brett Hartl
Government Affairs Director
Center for Biological Diversity
bhartl@biologicaldiversity.org
202-817-8121

Camilla Getz
Law Fellow
Environmental Health Program
Center for Biological Diversity
cgetz@biologicaldiversity.org

II. Guidance Documents Identification

The Center for Biological Diversity (Center) petitions the U.S. Environmental Protection Agency (EPA) to withdraw the guidance document: *Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs, U.S. Environmental Protection Agency—Endangered and Threatened Species Effects Determinations* (hereinafter “2004 Overview Guidance”)¹ to be withdrawn.

We request that EPA withdraw the related guidance document within the 2004 Overview Guidance “#70 Background on development of LOCs,” (Support Document #70) which cannot be found on any public-facing website, and all other “supporting documents” that are not valid guidance documents per EPA’s new final rule.

Furthermore, the Center also requests EPA withdraw the guidance document: *Guidelines for Ecological Risk Assessment-Risk Assessment Forum* (hereinafter “1998 Risk Assessment Guidance”)².

¹ U.S. ENVIRONMENTAL PROTECTION AGENCY, OVERVIEW OF THE ECOLOGICAL RISK ASSESSMENT PROCESS IN THE OFFICE OF PESTICIDE PROGRAMS-ENDANGERED AND THREATENED SPECIES EFFECTS DETERMINATIONS (Jan. 23, 2004) [hereinafter 2004 Overview Guidance] available at: <https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf>.

² U.S. ENVIRONMENTAL PROTECTION AGENCY, *Guidelines for Ecological Risk Assessment-Risk Assessment Forum*, EPA/630/R-95/002F (Apr. 1998) [hereinafter 1998 Risk Assessment Guidance] available at: https://www.epa.gov/sites/production/files/2014-11/documents/eco_risk_assessment1998.pdf.

First, the Center notes that EPA’s Final Rule: *Administrative Procedures for Issuance and Public Petitions Rule* (hereinafter “Final Rule”)³ does not explicitly require the petitioner to submit a separate petition for each guidance document that an entity seeks to withdraw. We believe that given the overlap and interrelated nature of the three guidance documents, and since the 2004 Overview Guidance incorporates by reference the 1998 Risk Assessment Guidance, it is appropriate to submit a single petition for the three guidance documents together. Because Support Document #70 is not available in an online format, we cannot confirm that such guidance document actually exists and believe it would be extremely inefficient to submit a separate petition for this document.

Second, the Center would like to note that neither the 2004 Overview Guidance nor the 1998 the Risk Assessment Guidance are included in the EPA Guidance Portal (last accessed November 16th) and do not have an EPA Identifier. By the plain text of the preamble of the proposed rule, EPA has therefore deemed that both of these documents have been rescinded and are no longer in force.⁴ As the EPA stated in its Response to Comments: “[t]his rule sets forth the procedures for posting active guidance documents and notes that guidance documents, as defined in this rule, not posted on the EPA Guidance Portal would be deemed rescinded.”⁵ Thus, the Center is only submitting this petition in an abundance of caution should EPA act inconsistently and arbitrarily in a *post-hoc* manner to resuscitate either guidance document. We only present this petition in the event EPA attempts to use the guidance documents now or in the future, and we seek to repeal them should EPA attempt an end-run around its own clearly articulated position regarding documents that cannot be found on the EPA portal. Should EPA agree that these have been deemed rescinded, the petition seeks to confirm that they are in fact permanently withdrawn and will never be utilized by EPA staff moving forward.

Additional Background on Guidance Documents:

The 1998 Risk Assessment Guidance set forth the ecological risk assessment process for reviewing the impacts of pesticides on the environment in general. It sets forth a framework that guided the EPA on analytical approaches to assess the effects of a pesticide on the soil, surface water, ground water, and on plants and animals, including endangered and threatened species.

The 2004 Overview Guidance set forth an ecological risk assessment process specifically for threatened and endangered species. The ecological risk assessment set forth several additional policies — specifically the use of “Levels of Concern” and “Risk Quotients” — that were announced for the first time in that guidance document. The document cites to Support Document #70 as the stated rationale for these policies, but this document does not appear to exist, and cannot be relied upon.

³ EPA Guidance; Administrative Procedures for Issuance and Public Petitions, 85 Fed. Reg. 66230 (Nov. 18, 2020) (to be codified at 40 C.F.R. pt. 2).

⁴ Rescinded guidance document means a document that would otherwise meet the definition of a guidance document or significant guidance document, but that the EPA may not cite, use, or rely upon except to establish historical facts.

⁵ U.S. EPA, *Summary of Public Comments and Responses for EPA Guidance; Administrative Procedures for Issuance and Public Petitions* at 27 (Aug. 2020) Docket EPA–HQ–OA–2020–0128 [hereinafter EPA Response to Comments].

By its own terms, both of these guidance documents clearly are “guidance documents.” Executive Order 13891 defines “guidance document” as “an agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation.”⁶ EPA follows this definition and defines “guidance document” as an “Agency statement of general applicability, intended to have future effect on the behavior of regulated parties, that sets forth a policy on a statutory, regulatory, or technical issue, or an interpretation of a statute or regulation.”⁷ As a historical fact, the EPA has used both of these guidance documents in its review and approval process during the registration of pesticide active ingredients and products. There are eleven exceptions to EPA’s definition of a “guidance document,” none of which apply to the 1998 Risk Assessment Guidance or the 2004 Overview Guidance.

EPA stated in its response to comments to EPA new final rule, “[t]o the extent that any particular document (regardless of what it is termed as or called) satisfies the definition of ‘guidance document’ in this regulation, the document would be subject to these procedures.”⁸ Further, “EPA does not intend to use this rule to parse the various nomenclatures and types of guidance that it uses.”⁹ The 2004 Overview Guidance fits within the definition of guidance document because the document is of general applicability, has affected and will continue to affect the behavior of regulated parties, and sets forth policy for EPA’s ecological risk assessment process. In particular, the 2004 Overview Guidance creates policy and guidance by establishing “Levels of Concern” (LOC) via “Risk Quotients” (RQ) for listed species.¹⁰ The 1998 Risk Assessment Guidance also meets this definition since it provided a foundation for the 2004 Overview Guidance and is cited throughout the 2004 document.

III. Relief Sought

The Center seeks the permanent withdrawal of the 2004 Overview Guidance in full. Additionally, the Center seeks the withdrawal of the 1998 Risk Assessment Guidance in full. To the extent that Support Document #70 still exists, the Center seeks the withdrawal of this guidance document.

IV. Interest of the Petitioner

The Center is a nonprofit environmental organization dedicated to the protection of species and their habitats through science, policy, and environmental law. The Center has more than 1.7 million members and online activists committed to the protection of endangered species. For thirty-one years, the Center has worked to protect imperiled plants and wildlife, open space, air and water quality, and overall quality of life for people and animals from toxic threats including pesticides.

⁶ Exec. Order No. 13891, 84 Fed. Reg. 199, 55235 (Oct. 9, 2019).

⁷ 85 Fed. Reg. 66230, 66237.

⁸ EPA Response to Comments.

⁹ 85 Fed. Reg. 66230.

¹⁰ See Section V(b) of this petition for elaboration.

The Center is significantly harmed by EPA's continued reliance on the guidance because the guidance documents are underprotective of endangered species and have allowed EPA to skirt its legal obligations for decades. Accordingly, the withdrawal of the 2004 Overview Guidance and 1998 Risk Assessment Guidance would better help protect the environment and force EPA to abide by the rule of law set forth by Congress, because it could no longer rely on guidance that allows a pesticide product to negatively impact threatened and endangered species nationwide.

V. Rationale for the Withdrawal of the 2004 Overview Guidance and 1998 Risk Assessment Guidance

The purpose of the 2004 Overview Guidance was to set forth specific processes that EPA would use to evaluate potential risks to endangered and threatened species from exposure to pesticides.¹¹ These assessments were purported to be conducted at the screening level or at a more refined species-specific level, and would follow a consistent approach based on (1) the EPA's 1998 Risk Assessment Guidelines, which the Center also petitions EPA to withdraw (2) the EPA's 2000 Risk Characterization Handbook and (3) EPA's Peer Review Handbook. For each assessment, EPA would purportedly first complete a "problem formulation" in which it defined the regulatory action, characterized the nature of the chemical stressor and pesticide use, identify assessment endpoints, and determine direct and indirect effects to listed species and their critical habitats. EPA would then conduct an "analysis phase" that would characterize the exposure to the pesticide, including the specific modeling needed for terrestrial and aquatic species, and assess the effects of the pesticide. At the final stage, EPA would purportedly complete a "risk characterization" that would integrate the exposure and effects data. This risk characterization would include several types of analysis, the limitations of which are discussed in greater detail below.

Critically, at this risk characterization phase, EPA would purportedly integrate its exposure and effects data to derive a "risk quotient" or "RQ" and then EPA would evaluate — as a policy matter — what action to take based on whether or not the RQ exceeded its "level of concern" or "LOC" or "LOCs." The 2004 Overview Guidance states the LOC is in fact "the policy tool for interpreting risk quotients" and states that these LOCs were derived based on Support Document #70 "Background on development of LOCs."¹² As explained by the EPA:

Risk characterization integrates the results of exposure and toxicity data to evaluate the likelihood of adverse ecological effects on non-target species. For most chemicals, the effects characterization is based on a deterministic approach using one point on a concentration-response curve... In this approach, OPP uses the risk quotient (RQ) method to compare exposure over toxicity. After risk quotients are calculated, they are compared to the Agency's LOCs. *These LOCs are the Agency's interpretative policy* and are used to analyze potential risk to non-target organisms and the need to consider regulatory action.¹³

¹¹ 2004 Overview Guidance at 7.

¹² See generally, *Id.*

¹³ *Id.* (Emphasis added).

As discussed later in this petition, LOCs are nothing more than arbitrary policy constructs that were created at some point after the publication of the 1998 Risk Assessment Guidance — perhaps in Support Document #70 — and simply announced to the public in the 2004 Overview Guidance. How, why, and specifically which LOCs the EPA chose to adopt at that time was simply a matter of executive fiat, the decision did not involve public comment, and as also discussed later, did not involve the two expert agencies on endangered species — the U.S. Fish and Wildlife Service and the National Marine Fisheries Service. Because there was no explanation for the basis for threshold determinations for LOCs and RQs in the 2004 Overview Guidance nor the 1998 Risk Assessment Guidance, the LOCs and RQs are nothing more than arbitrary and capricious policy choices, and are woefully inadequate in protecting endangered species from pesticides.

Section 7(a)(2) of the Endangered Species Act (ESA) requires the EPA to consult with the United States Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (collectively the “Services”) prior to registering any pesticide active ingredient or product to insure that such pesticide will not jeopardize the existence of any threatened or endangered species, or destroy or adversely modify the species’ critical habitat.¹⁴ Importantly, this requirement also applies to programmatic agency actions, including the promulgation of regulations and other policy guidance that harms listed species. The reason is simple — extinction is forever. Accordingly, “the strict substantive provisions of the ESA justify more stringent enforcement of its procedural requirements.”¹⁵

It is simply a matter of historical fact that the EPA failed to consult on its development of the 2004 Overview Guidance or the 1998 Risk Assessment Guidance. And because neither of these policy guidance documents required EPA to abide by the clear requirements of the ESA, many endangered species nationwide continue to be exposed to dangerous levels of pesticide contamination. Other than being compelled by court orders, over the past twenty-plus years, neither the 2004 Overview Guidance nor the 1998 Risk Assessment Guidance resulted in any on-the-ground conservation measures for listed species.¹⁶

The failure to consult with the Services had real-world consequences, namely that it allowed EPA to illegally conduct its pesticide evaluation processes using underprotective, analytically deficient methods and procedures for years. Many of these deficiencies are outlined in *Washington Toxics Coalition v. Department of Interior*,¹⁷ and include among other things, the failure to evaluate cumulative effects, synergistic impacts, “inert” ingredients, tank mixtures, and sublethal effects beyond growth and reproduction, such as olfactory communication and immune system health.¹⁸

As has been noted in hundreds of comment letters by the Center over the years, EPA’s pesticide exposure pathways models do not address *any* of the real-world complexities listed above.

¹⁴ 16 U.S.C. § 1536(a)(2).

¹⁵ *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985).

¹⁶ *Washington Toxics Coalition v. EPA*, 413 F.3d 1024 (9th Cir. 2005); *Northwest Coalition/or Alternatives to Pesticides v. Lyng*, 844 F.2d 588 (9th Cir. 1988).

¹⁷ *Washington Toxics Coal. v. U.S. Dep’t of Interior, Fish & Wildlife Serv.*, 457 F. Supp. 2d 1158, 1163 (W.D. Wash. 2006).

¹⁸ *Id.*

Instead, EPA evaluates a pesticide active ingredient in the abstract only, relying almost exclusively on industry-generated laboratory testing, and an inadequately populated database that fails to capture most of the scientific literature regarding the impacts of pesticides. Based on the questionable use of surrogate species¹⁹ — all of which are far less sensitive to pesticides compared to virtually any listed species — and dubious models like the “model farm pond” EPA has swept the impacts of pesticides under the rug for decades.

When EPA was forced to consult due to litigation losses, the deficiencies of the 2004 Overview Guidance become that much more apparent. As the Center has stated before, in the recent past, the NMFS completed approximately 676 effects determinations regarding the registration of a subset of pesticides that are used in the Pacific Northwest on listed salmonid species (counting each pesticide product’s effects on a separate listed species/ESU as a unique effects determination). Over the course of several biological opinions, the NMFS concluded that jeopardy and/or adverse modification of critical habitat to listed salmon and steelhead species would occur in 293 of those effects determinations. Of those 293 jeopardy/adverse modification findings, EPA concluded in 49 of those effects determinations that the pesticide would have “no effect” on a listed species and concluded 40 times that the pesticide was “not likely to adversely affect” a listed species.

In other words, over 30 percent of the time, EPA reached the opposite (and less protective) result — based on the analytical methods of the 2004 Overview Guidance and the 1998 Risk Assessment Guidance — compared to the NMFS regarding the effects a pesticide would have on a listed salmon and steelhead species. And of course, even more disturbingly, of the 293 jeopardy determinations made by NMFS since 2001, EPA has refused to implement a single RPA for any listed species under any circumstance for any pesticide.

The 2004 Overview Guidance and the 1998 Risk Assessment Guidance also completely ignore both the statutory requirement and real-world necessity of assessing impacts to critical habitat from pesticides. The destruction and the degradation of habitat remain the primary threat to the vast majority of listed species, a fact that Congress expressly noted when it passed the ESA in 1973.²⁰ Accordingly, the *recovery* of threatened and endangered species depends on sufficient habitat being protected and restored to ensure a species’ long term viability. One of the clearest areas where the EPA’s 2004 Overview Guidance fails to account for the needs of threatened and endangered species is the failure to address adverse modification of critical habitat *separately* as an independent analysis from the jeopardy one.

Section 7(a)(2) of the ESA requires all agencies to consult with the Services in order to (1) insure that their actions will not jeopardize any listed species and (2) insure against the destruction or adverse modification of a listed species’ critical habitat. While these two statutory mandates do partially overlap, some agency actions can adversely modify critical habitat *without* causing jeopardy.²¹ In fact, many federal actions, including the use of pesticides may adversely modify habitat but not cause enough harm to create a likelihood of jeopardy.

¹⁹ *Id.*

²⁰ D.S. Wilcove et al., 1988. *Quantifying Threats to Imperiled Species in the United States: Assessing the Relative Importance of Habitat Destruction, Alien Species, Pollution, Overexploitation, and Disease*, 48 *BIOSCIENCE* 607.

²¹ Dave Owen, *Critical Habitat and the Challenge of Regulating Small Harms*, 64 *FLA. L. REV.* 141 (2012).

It is quite common that an agency action will occur in an area that is designated as critical habitat but is unoccupied by the species at the time the activity occurs. For example, a pesticide could be applied to the environment at a time of year when a listed species is not present, such as scenarios where listed salmon and steelhead are only present within freshwater portions of their critical habitat at certain times of the year, yet a pesticide application could impact critical habitat for that species at any time of year by killing prey that they will depend upon later in the year.

EPA's 2004 Overview Guidance risk assessment process focuses on direct harm to living organisms and at best contemplate a screening-level analysis of indirect effects. Thus, EPA made a policy choice as to whether it will provide listed species the benefit of the doubt when it conducts its risk assessment with respect to critical habitat. And unfortunately, EPA has chosen to not give listed species the benefit of the doubt when it comes to critical habitat.

The most significant way that EPA fails to give the benefit of the doubt to listed species is its arbitrary use of LOCs themselves. By its own description, EPA purportedly integrates the results of pesticide exposure and toxicity data to develop an "RQ" for each pesticide. Once the RQ has been established for a particular pesticide, EPA then evaluates it to its pre-established LOCs for different types of organisms. This policy-tool then determines if the use of a pesticide crosses some threshold of acceptable risk.

Unfortunately, the EPA's policy tool — the LOCs — are just ludicrously absurd.

The LOC that triggers additional restrictions for impacts to any non-target organisms is set at 0.5 ($RQ > 0.5$). For any threatened or endangered *aquatic* wildlife species, the LOC for acute impacts is set at 0.05 ($RQ > 0.05$). For any terrestrial mammal or bird, the LOC for acute impacts is set at 0.1 ($RQ > 0.1$). Why were these numbers chosen? EPA's approach in the 2004 Overview Guidance does not align even with the most basic principles of conservation biology, let alone the ESA's broad mandate to provide the benefit of doubt to threatened and endangered species.

Why should a threatened aquatic species be given a greater degree of protection than an endangered terrestrial species? Why should threatened aquatic species be given the same degree of protection as endangered aquatic species? EPA doesn't even have specific LOCs for amphibians and reptiles, so what is EPA to do when it assesses a species that is aquatic for part of its lifecycle and terrestrial for another part of it? Threatened species, by definition, are at far less risk of extinction than endangered species. In the Pacific Northwest, there are dozens of endangered and threatened salmon and steelhead species. The threatened Oregon Coast Coho population numbers are in the hundreds of thousands, while the endangered Snake River sockeye salmon population numbers are in the tens to hundreds.²² Yet, both of these species would be considered "aquatic endangered species" under 2004 Overview Guidance's ecological risk assessment procedures. Why is it logical that the LOC should be the same for both species?

There is no scientific reason why aquatic species should have a lower LOC than terrestrial species if one considered the conservation status of any particular species. Just as there may be

²² *Northwest Environmental Advocates v. U.S. Environmental Protection Agency*, No. 05-cv-01876-AC (D. Or. Feb. 28, 2012).

two aquatic species facing different degrees of imperilment, there are many threatened aquatic species that are far more secure than terrestrial endangered species. A bird or mammal down to its last few hundred individuals can be exposed to far greater risks from pesticides for no other reason than it happens to be a bird or mammal.

There is no reason why the LOC for *all* threatened and endangered species couldn't just be set at the same very low and uniform level. If EPA wanted to be truly precautionary in its approach to pesticides, it could easily set the LOC for all threatened and endangered species at 0.01 or even 0.001. Even better, the EPA could adopt the approach of the European Union on pesticides and require all pesticide registrants to prove that their products are 100% safe, rather than requiring EPA to prove that the pesticide is harmful to listed species.²³ In other words, if EPA wanted to, it could follow the law and “give the benefit of the doubt to the species.”²⁴

At its core, LOCs are arbitrary policy choices of EPA, supported by a document that may or may not exist, contained within a guidance document that had no public comment process in 2004 and which EPA has deemed rescinded, loosely based on another guidance document from 1998 that is outdated and has also been deemed rescinded.

Accordingly, we request the guidance documents be permanently withdrawn.

Respectfully Submitted,



Brett Hartl
Government Affairs Director
Center for Biological Diversity

Camilla Getz
Law Fellow, Environmental Health Program
Center for Biological Diversity

²³ European Commission Regulation EC 1107/2009 & Directive 91/414/EEC. Available at: http://ec.europa.eu/food/plant/plant_protection_products/legislation/index_en.htm.

²⁴ *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988) (quoting H.R. Conf. Rep. No. 96-697, 96th Cong., 1st Sess. 12, *reprinted in* 1979 U.S. Code Cong. & Admin. News 2572, 2576).